

Revised Claim Set for 09/744,431 (X-12383M) after Amendment

141. (New) A stable, pharmaceutically acceptable, solution formulation suitable for multi-use comprising FSH or an FSH variant, containing an alpha and a beta subunit and a preservative selected from the group consisting of phenol, m-cresol, p-cresol, o-cresol, chlorocresol, benzyl alcohol, alkylparaben, benzalkonium chloride, benzethonium chloride, sodium dehydroacetate, thimerosal, and mixtures thereof, in an aqueous diluent; wherein, when stored for 3 months at room temperature or below, the solution formulation retains the same level of heterodimer content as that of a control formulation that is identical to the solution formulation except for lacking preservative, and that is stored under the identical conditions.

142. (New) A stable, pharmaceutically acceptable, solution formulation suitable for multi-use comprising FSH or an FSH variant, containing an alpha and a beta subunit and a preservative selected from the group consisting of phenol, m-cresol, p-cresol, o-cresol, chlorocresol, benzyl alcohol, alkylparaben, benzalkonium chloride, benzethonium chloride, sodium dehydroacetate, thimerosal, and mixtures thereof, in an aqueous diluent; wherein, when stored for 237 days at room temperature or below, the solution formulation retains the same level of heterodimer content as that of a control formulation that is identical to the solution formulation except for lacking preservative, and that is stored under the identical conditions.

143. (New) The solution formulation of either Claim 141 or Claim 142, wherein the FSH is human FSH.

144. (New) The solution formulation of either Claim 141 or Claim 142, wherein the FSH is an FSH variant, wherein the α -subunit has an amino acid sequence given in SEQ ID NO:5:

APDVQDCPECTLQENPFFSQPGAPILQCMGCCFSRAYPTPLRSKKTMLVQKNVTSEST
CCVAKSYNRVTVMGGFKVENHTACHCSTCYHKS;

and wherein the β -subunit has an amino acid sequence given in SEQ ID NO:11:

NSCELTNITIAIEKEECRFCISINTTWCAGYCYTRDLVYKDPARPKIQKTCTFKELV
YETVRVPGCAHHADSLYTYPVATQCHCGKCDSDSTDCTVRGLGPSYCSFGE.

145. (New) The solution formulation of either Claim 141 or Claim 142, wherein the preservative is benzyl alcohol.

146. (New) The solution formulation of Claim 145, wherein the FSH is human FSH.

147. (New) The solution formulation of either Claim 141 or Claim 142, wherein the preservative is m-cresol.

148. (New) The solution formulation of Claim 147, wherein the FSH is an FSH variant, wherein the α -subunit has an amino acid sequence given in SEQ ID NO:5:

APDVQDCPECTLQENPFFSQPGAPILQCMGCCFSRAYPTPLRSKKTMLVQKNVTSEST
CCVAKSYNRVTVMGGFKVENHTACHCSTCYHKS;

and wherein the β -subunit has an amino acid sequence given in SEQ ID NO:11:

NSCELTNITIAIEKEECRFCISINTTWCAGYCYTRDLVYKDPARPKIQKTCTFKELV
YETVRVPGCAHHADSLYTPVATQCHCGKCDSDSTDCTVRGLGPSYCSFGE.

149. (New) The solution formulation of either Claim 141 or Claim 142, wherein the concentration of FSH or FSH variant in the solution formulation is between about 50 $\mu\text{g/mL}$ and about 200 $\mu\text{g/mL}$.

150. (New) The solution formulation of Claim 149, further comprising a buffer.

151. (New) The solution formulation of Claim 149, further comprising an isotonicity agent.

152. (New) A vial containing the solution formulation of either Claim 141 or 142.

153. (New) A cartridge containing the solution formulation of either Claim 141 or 142.

154. (New) An article of manufacture comprising a vial containing the solution formulation of either Claim 141 or 142.

155. (New) An article of manufacture comprising a cartridge containing the solution formulation of either Claim 141 or 142.

156. (New) An article of manufacture comprising a first vial comprising lyophilized FSH or an FSH variant and a second vial comprising a preservative selected from the group consisting of phenol, m-cresol, p-cresol, o-cresol, chlorocresol, benzyl alcohol, alkylparaben, benzalkonium chloride, benzethonium chloride, sodium dehydroacetate, thimerosal, and mixtures thereof, in an aqueous diluent, wherein upon reconstitution of the lyophilized FSH or an FSH variant in the first vial with the contents of the second vial, the solution formulation of either Claim 141 or 142 is produced.

157. (New) A method of treating infertility, comprising administering to a patient in need thereof the formulation of either Claim 141 or Claim 142.

158. (New) A process for preparing the formulation of either Claim 141 or Claim 142, comprising admixing FSH or an FSH variant, containing an alpha and a beta subunit, and a preservative selected from the group consisting of phenol, m-cresol, p-cresol, o-cresol, chlorocresol, benzyl alcohol, alkylparaben, benzalkonium chloride, benzethonium chloride, sodium dehydroacetate, thimerosal, and mixtures thereof, in an aqueous diluent.